SCIENTIFIC CORRESPONDENCE

The use of surgical facemasks during cataract surgery: is it necessary?

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Aim: To assess whether facemask utilisation by the surgeon during cataract surgery has any effect on the bacterial load falling onto the operative site.

Method: Prospective randomised masked study. Consent was obtained from 221 patients. Cases were randomised to wearing a new mask or not wearing any mask throughout the procedure. Blood agar settle plates were placed adjacent to the patient's head in the operative field. Duration of procedure was noted. Plates were incubated and read at 48 hours. Colony forming bacteria were counted and identified.

Results: There were significantly fewer organisms cultured when the surgeon used a facemask (p=0.0006). The majority of organisms were *Staphylococcus epidermidis*, *Bacillus* spp, and *Diphtheroid* spp; however *Staphylococcus aureus* and *Pseudomonas aeruginosa* were cultured on several occasions. There were no cases of infective complication.

Conclusions: The main purpose of an operating mask is to prevent bacteria falling on to the operative site from the surgeon's oropharynx or nasopharynx with the concomitant theoretical risk of infective complication. Operating masks were shown to have a significant effect on the volume of bacterial organisms falling to the operative site; however, whether this is clinically significant is unknown.

The use of surgical face masks for prevention of contamination during surgical procedures was first advocated in 1897 by Mikulicz,[1] a German physician. Since then there have been numerous studies attempting to determine whether the use of face masks has a significant effect on reducing surgical wound infection.[2–10] Unfortunately the evidence in the literature has often been conflicting with little definitive guidance offered.

In the field of cataract surgery the major infective complication of concern is postoperative bacterial endophthalmitis. This study was designed to determine whether wearing a surgical facemask during cataract surgery reduces the volume of potentially infective organisms falling on to the operative site.

METHODS

Consecutive patients undergoing phacoemulsification cataract surgery were recruited. There were no patient exclusion criteria. If the surgeon had a symptomatic upper respiratory tract infection then that operating list was excluded from the study.

Ethics committee approval was obtained and consent obtained from 221 patients. Cases were randomised to group A "with mask" or group B "without mask."

All operations were carried out in ophthalmic theatres fitted with high efficiency particulate air (HEPA) filtering systems providing positive pressure airflow and a complete change in theatre atmosphere 20 times per hour. The scrub nurse wore a new surgical facemask throughout. None of the other theatre staff wore face masks.

The eye was cleaned with aqueous Betadine and a surgical adhesive drape was placed. A drop of aqueous Betadine was placed in the conjunctival sac. Cataract surgery was carried out by phacoemulsification via a superior or temporal corneal section. Subconjunctival Betnesol (4 mg) and cefuroxime (125 mg) (gentamicin substituted if allergic) were administered at the end of the procedure.

Masks used were Johnson and Johnson Medical Surgine anti-fog masks; 14 cm diameter blood agar settle plates were specially prepared using aseptic technique.

In group A the surgeon wore a new facemask and in group B the surgeon did not wear a facemask throughout. After placement of the surgical drape the settle plate (test plate) was secured adjacent to the patient's head on the operative side in the sterile field.

In 15 randomly selected cases carried out by a temporal incision a settle plate was placed at the side of the patient's head opposite the operative side (temporal section control plate). In 15 randomly selected superior section cases a settle plate was placed on the patient's chest within the sterile field to act as a control (superior section control plate).

During six randomly selected cases five settle plates were placed around the theatre to act as background measures (background plates). One plate was placed on the patient's abdomen outside the operative field. One of each of the remaining settle plates were placed on stands at the same height as the eye at a distance of 1 metre from each corner of the operating table.

A specified member of the circulating theatre staff noted the duration of the operation and any adverse events such as coughing or sneezing.

The settle plates were incubated for 48 hours at 37°C in a 5% carbon dioxide incubator and then read by a microbiologist. The total colony forming units (CFUs) were counted and the organisms were identified to species level. Bacterial growth was grouped into *Coliform* spp, *Staphylococcus aureus*, *Staphylococcus epidermidis*/*Bacillus* spp/*Diphtheroid* spp (these three species grouped together), *Pseudomonas* spp, and *Streptococcus* spp.

Statistical methodology

Results from the group where a mask was worn were used to derive cut-offs for deposition rates (CFU/min). The proportions of each group that breached this cut-off were compared using the χ^2 test. Confidence intervals for the difference between groups were obtained using a method developed by Newcombe.[11] The CFUs from the test plates paired with control plates were compared to the CFU of the control plates using the Wilcoxon signed rank test. The Mann-Whitney U test was used to compare absolute CFUs between test plates and background plates, and between background and control plates.
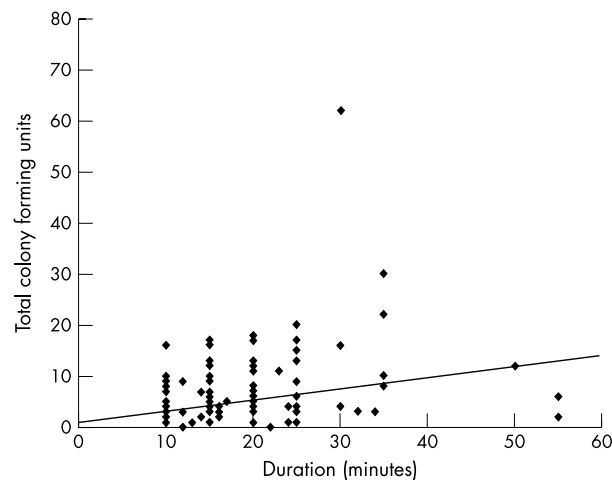
Figure 1 Scatter graph of total CFU count versus duration for group A (mask worn). Line of best fit: $y = 0.39x$, $r = 0.07$.
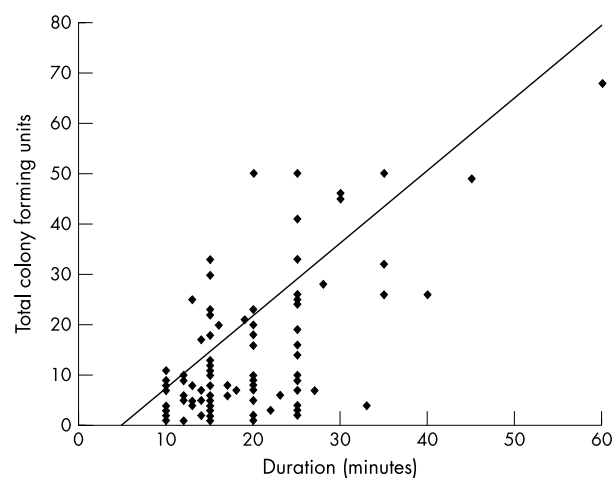

Figure 2 Scatter graph of total CFU count versus duration for group B (no mask worn). Line of best fit: $y = 1.06x$, $r = 0.64$.

RESULTS

One operating list (five patients) was excluded from the study because the operating surgeon experienced symptoms of an upper respiratory tract infection.

There were three adverse events; two single coughs in the masked surgeon group (total CFU = 3 and 5 respectively) and one single cough in the unmasked group (total CFU = 14).

One hundred and nine cases were randomised to group A (mask worn) and 112 cases were randomised to group B (no mask worn). One hundred and eighteen cases were under-

taken via a temporal section and 103 cases were done via a superior approach.

Total colony counts plotted against duration of procedure are shown in Figures 1 and 2 for groups A and B respectively.

Rate of deposition was calculated by dividing colony counts by duration of operation. An arbitrary cut-off point of 1 CFU/minute was taken for statistical purposes. In group A, five of 109 cases (4.6%) compared with 22 of 112 cases (19.6%) in group B attained a CFU deposition rate of more than 1 CFU/minute. Comparing data by χ^2 test, group B had higher deposition rates, a statistically significant difference of 15%, 95% CI (6.6% to 23.8%), p=0.0006.

Groups A and B were compared for "superior" and "temporal" section subgroups. For both subsets there were statistically lower counts in group A compared to group B, p values = 0.016 and 0.006 respectively.

There was no significant difference between the temporal section/mask worn group and the superior section/mask worn group (p=0.16). There were significantly higher test plate colony counts in the temporal section/mask not worn group compared to the superior section/mask not worn (p=0.046).

Counts on the test plates where a control plate was also placed (n=30) were significantly higher than those on the control plates (p<0.001).

The Mann Whitney U-test was used to compare background plate counts (n=30) with control plate counts (n=30). Counts on the background plates were significantly higher than those on control plates (p<0.001).

Eighty four per cent of all bacterial growth was *Staphylococcus epidermidis*, *Bacillus species*, or *Diphtheroid species*.

The various types of organism cultured are presented in Table 1.

DISCUSSION

There is a relative paucity of information in the literature offering definitive evidence with regard to the practice of surgical facemask utilisation for the prevention of postoperative infective complications. The necessity for routine use of surgical facemasks during interventional procedures has been questioned.[2–4] The majority of the clinical research carried out to date on the topic concern general surgical and gynaecological procedures.

Epidemiological evidence suggesting the theory of droplet infection emerged in the 1920s when strains of haemolytic streptococci isolated from patient's wounds were found to be identical to those recovered from the oropharynx of surgical and obstetrical teams.[12]

Berger *et al*[5] studied the effects of surgical mask use on bacterial contamination of the operative field during cardiac catheterisation. Mask position was varied for each procedure: on, off, or below the nose. The number of bacterial colonies recoverable was significantly higher in the unmasked group. Although there were higher counts recoverable from the "mask below nose" group than the "masked" group these values did not reach statistical significance.

Table 1 Number of cases where an organism was grown, the median values, interquartile range, and range of colony forming units detected in those cases

Organism grown	Group A, mask worn			Group B, no mask worn		
	Number of cases	Median CFU (interquartile range)	Range of CFU	Number of cases	Median CFU (interquartile range)	Range of CFU
Coliform spp	28	1 (1, 2)	1–9	18	1 (1, 2.25)	1–14
Staph aureus	11	2 (1, 5)	1–6	26	2 (1, 3)	1–6
S epi/Bacillus/Diphth	105	4 (2, 8)	0–63	110	6.5 (4, 14.25)	1–68
Pseudomonas spp	6	1.5 (1, 9)	1–30	7	1 (1, 2)	1–6
Streptococcus spp	9	1 (1, 5.5)	1–10	15	1 (1, 4)	1–15

Philips et al[6] examined the bacterial contamination at a distance of 30 cm from a subject's mouth when a mask was or was not utilised. Organisms grown were upper respiratory tract commensals including coagulase negative staphylococci and α haemolytic streptococci. The unmasked group showed a statistically significant increase in surface bacterial growth. They concluded that facemasks should be worn when the operator is in close proximity to the sterile field. McLure and colleagues[7] confirmed this finding in a similar study; however, when Tunevall and Jorbeck[8] looked at the effect of mask use on the number of bacterial CFUs in the vicinity of thyroid operations, they found no statistical difference between groups.

Only one large scale prospective randomised clinical trial has directly addressed the effect of facemask use on general surgical wound infection, finding no significant difference between wound infection rates.[9]

Care must be taken when attempting to extrapolate the results of the aforementioned studies to ophthalmic surgery. In particular, correlating higher surgical wound infection rates with the potential for endophthalmitis may be inappropriate.

The exact pathogenesis of endophthalmitis after cataract surgery is unknown. The source of the bacterial inoculum required to cause the infection and the method of pathogen intraocular access has not been fully identified. Potential sources of bacterial contamination are from the conjunctival and lid margin flora, from contaminated surgical intraocular instruments, or theoretically from infective organisms falling onto the eye during the procedure.[13–15]

This study was designed to investigate bacterial load falling on to the operative site and, because of the relatively small numbers studied, it is not possible to extrapolate the effect on the rate of endophthalmitis.

In the present study, the difference in colony counts between the two groups is relatively small (15%, 95% CI (6.6% to 23.8%)) and the clinical significance, if any, of this difference is a matter for speculation.

We have shown that the use of a surgical facemask during cataract surgery leads on to a statistically significant reduction in the volume of bacterial organisms falling on to the operative site ($p < 0.001$). This difference is clearly illustrated by Figures 1 and 2. Colony counts were significantly higher ($p < 0.001$) on the test plates when compared to the control plates indicating that the surgeon's proximity is indeed causative of increased bacterial environmental load. Background counts were significantly higher ($p < 0.001$) than those on control plates suggesting that the environment in the operative area is relatively free of airborne bacterial contamination when compared to the rest of the theatre. Background plates were placed in the open and in close proximity to unmasked theatre staff potentially contributing to excessive bacterial counts. It is thus reasonable to assume that the surgeon's presence and subsequent liberation of organisms into the air over the plates (and thus by inference the operative site) is causative of the higher colony counts on the test plates.

Interestingly, when no mask was worn there was a significantly higher bacterial deposition rate in the temporal group than the superior section group ($p = 0.046$). This difference is probably artefact related to study design, with the slightly closer placement of test plate to the surgeon when a temporal approach is used, the plate being placed immediately beneath them. This would theoretically result in slightly higher counts and supports the hypothesis that the colony counts on the settle plates are related to the surgeon's proximity.

The numbers are unfortunately too small to allow effective statistical analysis between the nature of infective organisms grown in each group; however, it is seen that in many cases, regardless of group allocation, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, and *Staphylococcus epidermidis* were cultured. All of these are certainly potential intraocular

pathogens.[15 16] Unless a causal link between bacterial organisms falling onto the operative site and the pathogenesis of endophthalmitis is made, the implications of the findings of this study are unclear. However, it may be reasonable to hypothesise an increased risk of endophthalmitis with an increased bacterial load in the operative field.

It is the therefore the authors' belief that, although the risk of endophthalmitis is low, the potential consequences of this complication are so severe that despite the unproved link between bacterial load and endophthalmitis rate, the surgeon should attempt to minimise even theoretical risks and should routinely wear a surgical facemask for cataract surgery. In order to offer definitive evidence based guidance further research is required perhaps involving larger sample sizes thereby allowing statistical comment on endophthalmitis rates.

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